

Fingertip Pulse Oximeter

USER MANUAL

Ver2.0C635

SM-230/SM-240

General Description

Oxygen Saturation is a percentage of Oxyhemoglobin (HbO₂) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, it is consistency of Oxyhemoglobin in blood. It is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

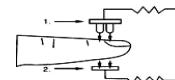
The fingertip pulse oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis, and the pulse rate and oxygen saturation will appear on the display. It has been proven in clinical experiments that it also features high precision and repeatability.

Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(RHb) and Oxyhemoglobin (HbO₂) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube



Precautions For Use

- 1 Before use, carefully read the manual.
- 2 Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
- 3 The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ measurement.
- 4 Do not use the fingertip pulse oximeter in an MRI or CT environment.
- 5 Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
- 6 Do not use the fingertip pulse oximeter in an explosive atmosphere.
- 7 The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- 8 Check the pulse oximeter sensor application site every 4 hours to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
- 9 Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- 10 Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- 11 This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
- 12 Portable and mobile RF communications equipment can affect medical electrical equipment.

Rx only: "Caution: Federal law restricts this device to sale by or on the order of a physician."

Inaccurate measurements may be caused by

- 1 Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin);
- 2 Intravascular dyes such as indocyanine green or methylene blue;
- 3 High ambient light. Shield the sensor area if necessary;
- 4 Excessive patient movement;
- 5 High-frequency electrosurgical interference and defibrillators;
- 6 Venous pulsations;
- 7 Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- 8 The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- 9 The patient is in cardiac arrest or is in shock;
- 10 Fingernail polish or false fingernails;
- 11 Weak pulse quality (low perfusion);
- 12 Low hemoglobin;

Product Properties

- 1 Operation of the product is simple and convenient.
- 2 The product is small in volume, light in weight and convenient to carry.
- 3 Power consumption of the product is low and the two AAA batteries can be operated continuously for 30 hours.
- 4 A low voltage warning will be indicated when battery voltage is low and normal operation of the oximeter might be influenced.
- 5 The product will automatically power off when there is no signal for longer than 8 seconds.

Intended Use

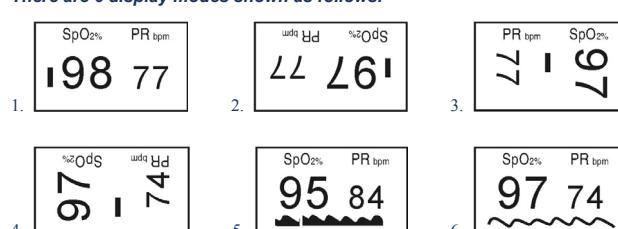
Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuous monitoring.

Operation Instructions

- 1 Install two AAA batteries according to the Battery Installation instructions listed above in the right column
- 2 Open the clamp as illustrated in the picture below.
- 3 Fully insert one fingertip into the silicone hole of the oximeter before releasing the clamp.
- 4 Press the switch button once on front panel.
- 5 Keep your finger still during measurement.
- 6 Read corresponding data from display screen.
- 7 Press the button again to toggle between six display modes.

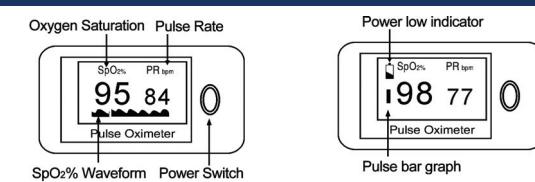


After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes shown as follows:



Holding the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default level is level four.

Front Panel



Patient pulse quality signals are indicated by bar graph. The bar is graded as 10 levels, if the strength is level 2 to 3, the pulse signal is inadequate.

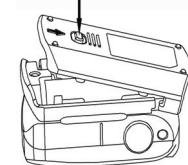
Product Accessories

- 1 One lanyard
- 2 Two AAA batteries
- 3 One instruction manual

Battery Installation

- 1 Press the button down on the rear panel and push the battery cover horizontally along the arrow shown in the following picture.
- 2 Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.

Press the button down !



Notes:

- ◇ Install the batteries with the correct polarity. Incorrect placement may cause damage to the bracket.
- ◇ Please remove the batteries if the pulse oximeter will not be used for long periods of time.

Using the Lanyard

- 1 Thread thinner end of the lanyard through the hanging hole.
- 2 Thread thicker end of the lanyard through the threaded end before pulling it tightly.



Warnings!

- 1 Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- 2 Do not hang the lanyard from the device's electrical wire.

Maintenance and Storage

- 1 Replace the batteries timely when low voltage lamp is lighted.
- 2 Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
- 3 Remove the batteries if the oximeter is not operated for a long time.
- 4 It is best to store the product in -20°C ~ +55°C and ≤93% humidity.
- 5 Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
- 6 Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter

Please use medical alcohol to clean the silicone touching the finger inside of Oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the finger being tested using alcohol before and after each test.

Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO₂ accuracy. The measured arterial hemoglobin saturation value (SpO₂) of the sensors is compared to arterial hemoglobin oxygen (SaO₂) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO₂ range of 70 - 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

The use life of the device is five years. when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:

- An error in the Possible Problems and solutions is displayed on screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

Specifications

1. Display Type

OLED display

2. SpO₂

Display range: 0-99%

Measurement range: 70-99%

Accuracy: 70%-99%: ±2%; 0%-69% no definition

Resolution: 1%

3. Pulse Rate

Display range: 0~254BPM

Measure range: 30-235 BPM

Accuracy: 30~99bpm, ±2bpm; 100~235bpm, ±2%

Resolution: 1BPM

4. Probe LED Specifications

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	940±10nm	2.0mW

5. Power Requirements

Two AAA alkaline Batteries

Power consumption: Less than 30mA

Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 30 hours.

6. Outline Dimension

Length: 58mm

Width: 32mm

Height: 37mm

Weight: 33g (without batteries)

Note: The dimensions of each device may differ slightly from the size that mentioned above.

7. Environment Requirements

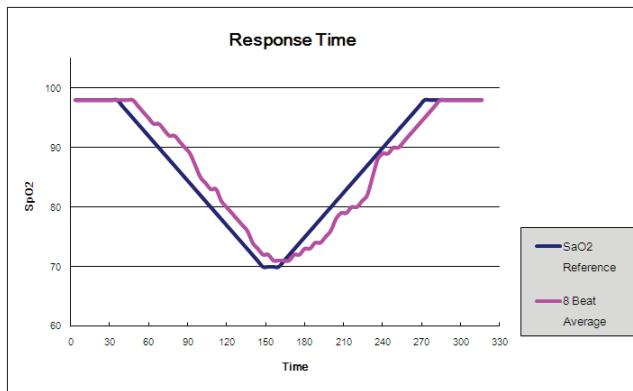
Operation Temperature: 5~40°C

Storage Temperature: -20~+55°C

Ambient Humidity: 15%~80% in operation, ≤93% in storage

8. Equipment Response Time

As shown in the right figure.
Response time of slower average is 12.4s.



9. Interference Resistance Capacity against Ambient Light

Device works normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter Tester.

10. Classification

According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART;
According to the method(s) of sterilization or disinfection recommended by the manufacturer: Equipment with method(s) of sterilization or disinfection recommended by the manufacturer;
According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE: EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE.
According to the degree of protection against ingress of water: IPX1
According to the mode of operation: CONTINUOUS OPERATION

Declaration

Guidance and Manufacturer's declaration – electromagnetic emissions-For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic emission			
2 The SM-230/SM-240 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of SM-230/SM-240 Pulse Oximeter should assure that it is used in such an environment.			
Emission test	Compliance	Electromagnetic Environment – guidance	
4 RF emissions CISPR 11	Group 1	The SM-230/SM-240 Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
5 RF emissions CISPR 11	Class B		
6 Harmonic emissions IEC 61000-3-2	N/A		
7 Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A		

Guidance and Manufacturer's declaration – electromagnetic immunity-For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic immunity			
The SM-230/SM-240 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the SM-230/SM-240 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SM-230/SM-240 Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the SM-230/SM-240 Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE UT is the a. c. mains voltage prior to application of the test level.

Guidance and Manufacturer's declaration – electromagnetic immunity – For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity			
The SM-230/SM-240 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the SM-230/SM-240 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the SM-230/SM-240 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SM-230/SM-240 Pulse Oximeter is used exceeds the applicable RF compliance level above, the SM-230/SM-240 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SM-230/SM-240 Pulse Oximeter.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the MD300C63 Pulse Oximeter

The SM-230/SM-240 Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SM-230/SM-240 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SM-230/SM-240 Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$	
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO ₂ or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's SpO ₂ value is too low to be measured	1. Retry by inserting the finger 2. There is excessive illumination 3. Try some more times. If you can make sure no problem is existing in the product, please go to a hospital timely for exact diagnosis.
SpO ₂ or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger 2. Be calmness
The oximeter can not be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. The battery power is too low to work	1. Normal 2. Replace the batteries
"Error3" or "Error4" is displayed on screen	1. Err 3 means the red emission LED is damaged 2. Err 4 means the infra-red emission LED is damaged	1. Check the red emission LED 2. Check the infra-red emission LED
Error 6	Err 6 means the screen is failure	Change the screen
"Error7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Check the emission LED and reception diode.

Symbol Definitions

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Type BF applied part.		No SpO ₂ Alarm		Date of Manufacture
	Attention, consult accompanying documents.	SN	Serial No.	PR bpm	Pulse rate (BPM)
IPX1	Protected against dripping water.		Storage temperature and relative humidity	% SpO₂	Oxygen saturation
	Low power indication				

Note: The illustrations used in this manual may differ slightly from the appearance of the actual product.

Manufactured for: iRoams Network

Address: 713 W. Duarte Rd #G810

Arcadia, CA 91007 USA

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